

REMARKS

Applicant respectfully requests entry of the amendments and reconsideration of the claims. Please cancel claims 1-3 and 19 without prejudice. Applicant retains the right to file one or more continuation applications claiming the cancelled subject matter. Claims 21 to 25 are now pending. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) and § 112, second paragraph.

Information Disclosure

Applicant requests the Examiner return an initialled copy of the Form 1449 filed December 17, 2008. Applicant believes this was an unintentional oversight since the Examiner indicated in the Office Action that he considered the reference.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 21-25 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. The Examiner states “[s]ince an artisan would not be able to practice the instant claim without knowing the specific host to administer the claimed method steps, the metes and bounds of the claimed subject matter are unclear.”

1. Applicants respectfully disagree. Applicants respectfully contend that it is not required that the claim recite someone or something to administer the claimed method steps. This is a common claim format in the life sciences. Commonly, this format of claim recites a subject or patient that receives administration according to the method steps.

2. Due to the reason recited immediately above, Applicant believes the Examiner erred and meant that the claim requires the method steps to be administered to a subject. Although Applicant does not agree, Applicant has amended claim 21 to recite a “method of increasing insulin sensitivity in a subject in need thereof,” and the method steps are administered to “said subject.”

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal

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of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-3, 19, and 21-25 as allegedly obvious over U.S. Patent Publication No. 2001/0056068 (Chwalisz et al.) in view of White & Campbell (Chapter 17 of Clinical Pharmacy & Therapeutics (Herfindal et al., ed.), p. 307-331, 1992). Applicant respectfully traverses.

To make a *prima facie* case of obviousness, the teachings of the prior art should have suggested the claimed subject matter to the person of ordinary skill in the art, and all the claim limitations must be taught or suggested in the references cited by the Examiner. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). As articulated by the Supreme Court, a combination is obvious if it is no more than the predictable use of known elements according to their established functions; and there was a reason to combine the known elements. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). To make a *prima facie* case of obviousness, "it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." *Id.* Applicants submit that the Examiner does not make a *prima facie* case of obviousness because the prior art does not suggest the claimed method of claims 21-25.

The pending claims recite a method of "increasing insulin sensitivity in a subject in need thereof" and administering "an effective amount of a nitric oxide donor or nitric oxide agonist for increasing insulin sensitivity in said subject." The Chwalisz et al. publication provides methods of treating a variety of diseases including hypertension, cardiovascular disease, diabetes mellitus, and male impotence. The background of the application discusses the role of nitric oxide in said diseases (col. 1 to col. 6). However, the role of nitric oxide is as a mediator of vascular tone and vasodilation (see, e.g., p. 1, ¶ [0005] to ¶ [0006] and p. 2-3, ¶ [0016]). Chwalisz et al. describe a relationship between nitric oxide deficiency and vascular effects but do not describe a relationship between nitric oxide and insulin sensitivity. Thereby, the art cited by the Examiner does not make a connection between a nitric oxide deficiency and insulin sensitivity. For at least this reason, the Examiner has not established that the prior art suggests the claimed subject matter, and thus has not established a *prima facie* argument of obviousness.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Summary

In view of the above amendments and remarks, the applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance prosecution of this application, the Examiner is invited to telephone the undersigned at the below listed telephone number.

Respectfully submitted,

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